

**PATENT COOPERATION TREATY**  
**PCT**  
**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 30 AUG 2005

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Applicant's or agent's file reference P13661PC/PC/RO	<b>FOR FURTHER ACTION</b>	See Form PCT/PEA/416
International application No. PCT/GB2004/003384	International filing date (day/month/year) 06.08.2004	Priority date (day/month/year) 07.08.2003
International Patent Classification (IPC) or national classification and IPC A61B5/00, A61B5/103		
Applicant UNIVERSITY OF DUNDEE et al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
- a. ☒ sent to the applicant and to the International Bureau a total of 6 sheets, as follows:
- ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
- ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
- b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand  07.06.2005	Date of completion of this report  29.08.2005
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer  Rick, K  Telephone No. +49 89 2399-7246 

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**Box No. I Basis of the report**

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1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

**Description, Pages**

1-14 as originally filed

**Claims, Numbers**

1-44 filed with telefax on 19.07.2005

**Drawings, Sheets**

1/3-3/3 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing *(specify):*
  - ☐ any table(s) related to sequence listing *(specify):*
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing *(specify):*
  - ☐ any table(s) related to sequence listing *(specify):*

\* If item 4 applies, some or all of these sheets may be marked "superseded."

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

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1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:
- ☐ the entire international application,
  - ☒ claims Nos. 43,44  
because:
    - ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):
    - ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
    - ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
    - ☒ no international search report has been established for the said claims Nos. 43,44
    - ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
      - the written form ☐ has not been furnished
      - ☐ does not comply with the standard
      - the computer readable form ☐ has not been furnished
      - ☐ does not comply with the standard
    - ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
  - ☐ See separate sheet for further details

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

Novelty (N)	Yes: Claims	3-5,32,33
	No: Claims	1,2,6-31,34-42
Inventive step (IS)	Yes: Claims	3-5,32,33
	No: Claims	1,2,6-31,34-42
Industrial applicability (IA)	Yes: Claims	1-42
	No: Claims	

**2. Citations and explanations (Rule 70.7):**

**see separate sheet**

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**Box No. VI Certain documents cited**

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**1. Certain published documents (Rule 70.10)**

and /or

**2. Non-written disclosures (Rule 70.9)**

**see separate sheet**

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement**

1. Reference is made to the following document:  
D1: US-A-5 769 791 (GOLDBERGER DANIEL S ET AL) 23 June 1998 (1998-06-23)  
D2: US-B-6 345 1941 (ZACH REUVEN D ET AL) 5 February 2002 (2002-02-05)
2. Document D1 (the references in parentheses applying to this document) relates to a palpation device comprising  
a first palpation assembly including a palpation member (grasper member 201, col. 18, l. 12 and Fig. 6) and a light source (fiber 245, col. 18, l. 20 and Fig. 6); and  
a second palpation assembly including a palpation member (grasper member 203, col. 18, l. 12 and Fig. 6) and light detecting means for detecting light emitted by the light source (fiber 246, col. 18, l. 20 and Fig. 6) and generating an image of a body part disposed between the first and second palpation members (col. 5, l. 42-43);  
wherein at least one of the first and second palpation members is movable with respect to the other member, to palpate a body part disposed there between (col. 18, l. 9-21 and Fig. 6).

Since the device of D1 is explicitly suitable to generate images (D1, col. 5, l. 42-43), all structural features mentioned in or derivable from present claim 1 are known from D1. Furthermore, the applicant is requested to note, that also the breast imaging device of D2 (e.g. col. 6, l. 45-54 and claims 1 and 4) contains all features of present claim 1 and is therefore considered to be at least suitable for the claimed purpose. Present **claim 1** thus **lacks novelty** so that the requirement of Art. 33(2) PCT is not met.

2. The same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding independent **claim 42**, which therefore is also considered **not new** in the sense of Art. 33(2) PCT.
3. Further **claims 2, 6-31 and 34-41** contain either features known per se from the prior art (see e.g. D1 or D2 and the corresponding passages cited in the search

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(SEPARATE SHEET)**

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report) or being slight constructional changes which come within the scope of the customary practice followed by persons skilled in the art. The applicant should in particular refer to the following passages:

- claim 2 see D1, temperature sensor 52, col. 14, l. 44;
- claims 6-9 see D2, col. 6, l. 52-54 and col. 11, l. 63 to col. 12, l. 4;
- claims 11-17 see D2, claims 1 and 4;
- claims 18-29 see D1, col. 7, l. 63-67 and col. 13, l. 11-20;
- claims 30 and 31 see D1, col. 4, l. 41-45 and claim 5;
- claims 34-41 see D2, col. 1, l. 64 to col. 2, l. 15, col. 3, l. 28-29.

Thus also claims 2, 6-31 and 34-41 do not meet the requirements of the PCT with respect to novelty (Art. 33(2) PCT) and inventive step (Art. 33(3) PCT).

4. However the combination of the features of dependent **claims 3 or 32**, are neither known from, nor rendered obvious by, the available prior art.

**Re Item VI**

**Certain documents cited**

**Certain published documents (Rule 70.10)**

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date ( <i>valid claim</i> ) (day/month/year)
WO03/077750	25/09/03	13/03/03	13/03/02

This Document, claiming priority dated 13/03/02 which is earlier than that of the present application, appears pertinent. No check has been made as to the validity of the priority dates, neither of that of the above mentioned document nor of that of the current application.

**CLAIMS**

1. A palpation device comprising:  
a first palpation assembly including a palpation member and a light source;  
and  
a second palpation assembly including a palpation member and light detecting means for detecting light emitted by the light source and generating an image of a body part disposed between the first and second palpation members;  
wherein at least one of the first and second palpation members is movable with respect to the other member, to palpate a body part disposed therebetween.
2. A palpation device as claimed in claim 1, comprising means for measuring at least one physical parameter of the body part.
3. A palpation device as claimed in claim 2, wherein the physical parameter of the body part is the resistance to deformation in response to an applied force.
4. A palpation device as claimed in either of claims 2 or 3, wherein the measuring means comprises force measuring sensors for measuring the force applied to the body part to produce a deformation.
5. A palpation device as claimed in any one of claims 2 to 4, wherein the measuring means comprises software for performing feature recognition and classification.
6. A palpation device as claimed in any preceding claim, wherein the first and second palpation members are independently moveable.
7. A palpation device as claimed in any preceding claim, wherein at least one of the first and second palpation members is moveable in at least two mutually perpendicular planes of motion, with respect to the body part.

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8. A palpation device as claimed in any preceding claim, wherein both palpation members are moveable in three mutually perpendicular planes of motion, with respect to the body part.
9. A palpation device as claimed in any preceding claim, wherein at least one of the first and second palpation members is generally planar.
10. A palpation device as claimed in any preceding claim, wherein the palpation device is for use in minimal access surgery (MAS).
11. A palpation device as claimed in any preceding claim, wherein the first palpation member comprises a light transmitting member.
12. A palpation device as claimed in claim 11, wherein the first palpation member is transparent.
13. A palpation device as claimed in any preceding claim, wherein the light source is embedded in the first palpation member.
14. A palpation device as claimed in any one of claims 1 to 12, wherein the light source is optically coupled to the first palpation member.
15. A palpation device as claimed in any preceding claim, wherein the first palpation member is optically shaped to transmit a substantial part of the light emitted by the light source through a surface of said first member, the surface adapted to be located adjacent the body part.
16. A palpation device as claimed in any preceding claim, wherein the second palpation member comprises a light transmitting member.
17. A palpation device as claimed in claim 16, wherein said light transmitting member is transparent.

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18. A palpation device as claimed in any one of claims 1 to 15, wherein the second palpation member comprises a light sensitive charge coupled device (CCD).

19. A palpation device as claimed in claim 18, wherein the CCD forms the whole of the second palpation member.

20. A palpation device as claimed in claim 18, wherein the CCD is embedded in the second palpation member.

21. A palpation device as claimed in claim 18, wherein the CCD is optically coupled to the second palpation member.

22. A palpation device as claimed in any one of claims 20 to 21, wherein the CCD is adapted to transduce received light into a 2-dimensional (2-D) pixel array for output to a display device to generate the image of the body part.

23. A palpation device as claimed in any preceding claim, wherein the light source comprises a light emitting diode.

24. A palpation device as claimed in any one of claims 1 to 22, wherein the light source comprises optical fibres.

25. A palpation device as claimed in any preceding claim, wherein the light detecting means comprises a charge coupled device (CCD).

26. A palpation device as claimed in any one of claims 1 to 24, wherein the light detecting means comprises a camera.

27. A palpation device as claimed in any one of claims 1 to 24, wherein the light detecting means comprises an endoscope.

28. A palpation device as claimed in any preceding claim, wherein the light detecting means is embedded in the second palpation member.

29. A palpation device as claimed in any one of claims 1 to 27, wherein the light detecting means is optically coupled to the second palpation member.

30. A palpation device as claimed in any preceding claim, wherein the first and second palpation members are moveable between an insertion position and a use position.

31. A palpation device as claimed in claim 30, wherein, in the insertion position of the first and second palpation members, the palpation device is of reduced dimensions compared to the use position of said palpation members.

32. A palpation device as claimed in either of claims 30 or 31, wherein the first and second palpation members each comprise at least two planar sub-plates, pivotally coupled together for movement between the insertion and use positions.

33. A palpation device as claimed in claim 32, wherein a number of separate images of the body part are obtained and are adapted to be patched together using suitable software.

34. A palpation device as claimed in any preceding claim, wherein the device is adapted to be mounted on a support arm having means for detecting the location and orientation of the palpation device.

35. A palpation device as claimed in any preceding claim, wherein the light source is adapted to emit light of a frequency in the visible spectrum.

36. A palpation device as claimed in any preceding claim, wherein the light source is adapted to emit structured light.

37. A palpation device as claimed in any preceding claim, wherein the light source is adapted to emit light of a frequency in the infra-red spectrum.

38. A palpation device as claimed in any preceding claim, wherein the device further comprises detecting means for detecting motion of at least a portion of the body part relative to at least one of the first and second palpation assemblies.

39. A palpation device as claimed in claim 38, wherein the detecting means is for detecting motion of said portion of the body part relative to the palpation members of at least one of the first and second palpation assemblies.

40. A palpation device as claimed in either of claims 38 or 39, wherein the detecting means comprises at least one point of reference.

41. A palpation device as claimed in claim 40, wherein the detecting means comprises a visible grid provided on each palpation member.

42. A palpation simulation device comprising:  
a first palpation assembly including a palpation member and a light source;  
and

a second palpation assembly including a palpation member and light detecting means for detecting light emitted by the light source and generating an image of a body part disposed between the first and second palpation members;

wherein at least one of the first and second palpation members is moveable with respect to the other member, to palpate a body part disposed therebetween.

43. A method of palpating a body part, the method comprising the steps of:  
providing a first palpation assembly including a palpation member and a light source;

providing a second palpation assembly including a palpation member and light detecting means for detecting light emitted by the light source and generating an image of a body part disposed between the first and second palpation members;

locating the first and second palpation assemblies with a body part disposed therebetween;

generating an image of said body part; and

moving at least one of the first and second palpation members relative to said other member, to palpate the body part.

- 5 44. A method of simulating palpation of a body part, the method comprising the steps of:
- providing a first palpation assembly including a palpation member and a light source;
- 10 providing a second palpation assembly including a palpation member and light detecting means for detecting light emitted by the light source and generating an image of a body part disposed between the first and second palpation members;
- locating the first and second palpation assemblies with a body part disposed therebetween;
- generating an image of said body part; and
- 15 moving at least one of the first and second palpation members relative to said other member, to palpate the body part.

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